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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,838	02/12/2004	Mark K. Wedel	FMDL0001US	5903

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/777,838	Applicant(s) WEDEL ET AL.	
	Examiner Dana Shin	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-3,7 and 8*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/J. E. Angell/
Primary Exmainer AU1635

Continuation of 3. NOTE: Applicant has added 19 new claims, claims 9-27. See MPEP 714.13, which states that applicants cannot, as a matter of right, amend any finally rejected claims, except when an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some way requires only cursory review by the examiner. Since the newly entered claims require more than mere cursory review, the claim amendments filed on July 18, 2007 are not entered.

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 USC §112 1st paragraph, written description and enablement rejections applied to claims 1-3 and 7-8.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments filed on July 18, 2007 are not persuasive. Applicant is correct that the instantly claimed "pouchitis" is a species of generic disease and the antisense oligonucleotide of SEQ ID NO:1 is a species of generic antisense oligonucleotides claimed in US 6,169,079 B1. However, applicant further contends that "pouchitis" and "SEQ ID NO:1" are not obvious variants of the claimed "disease with an inflammatory component which is modulated by changes in human ICAM-1" and the antisense composition comprising "SEQ ID NO:1". Applicant's attention is directed to the fact that the instantly claimed SEQ ID NO:1 is located in the 3'-UTR of the ICAM-1. The specification of US 6,169,079 B1 expressly teaches that a perferred antisense oligonucleotide is specifically hybridized with a sequence in the 3'-UTR. See column 10. It also teaches that "The oligonucleotides used in accordance with this invention may be conveniently and routinely made through the well-known technique of solid phase synthesis." See column 10. It further discloses a full-length ICAM mRNA sequence in Figure 1, and teaches that "any of the similar oligonucleotides which persons of ordinary skill in the art can prepare from knowledge of the preferred antisense targets for the modulation of the synthesis of inflammatory cell adhesion molecules." See column 12. The specification of US 6,169,079 B1 discloses that the antisense pharmaceutical composition can be administered in a number of ways including rectral administration and can be formulated for suppositories. See column 9. Accordingly, the generic scope of the claimed method in the reference claims of US 6,169,079 B1 embraces the narrow scope of the instantly claimed invention and since the US patent expressly teaches that any one of ordinary skill in the art can locate a perferred antisense target for modulation of inflammatory cell adhesion molecules given that the target ICAM-1 mRNA sequence is provided, the instantly claimed invention is an obvious variation of the generic, broad claims in the US patent. Accordingly, claims 1-3 as well as claims 7-8 (by claim dependency) remain rejected.

With regard to the obviousness-type double patenting rejection of claim 1 over claims 2 and 4 of US Patent 5,591,623 in view of Patel et al., applicant argues that the instant claim recites a new use, the "in vivo treatment of pouchitis in a human", which is not recited in the US Patent claims. Applicant is correct that the reference claims are drawn to "in vitro" methods while the present claims are drawn to "in vivo" methods; however, both methods comprise the same antisense compound comprising the identical 20-mer target sequence of the ICAM-1 mRNA. Applicant's attention is directed to MPEP §801, which teaches that "A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined appliation claim is either anticipated by, or would have been obvious over, the reference claims." In light of the guidance provided in MPEP, the instantly claimed method is an obvious variation of the invention claimed in the patent because the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection. Since Patel et al. taught patients with pouchitis have high level of ICAM-1 expression, and since the antisense compound claimed in the reference claims was known to inhibit ICAM-1 expression in cells, it would have been obvious to one of ordinary skill in the art to use the antisense compound of the reference claims for treating patients with pouchitis by reducing the level of ICAM-1 expression via the ICAM-1 specific antisense compound of US Patent 5,591,623. One of ordinary skill in the art would have been motivated to make and use a method of treating pouchitis in a patient comprising adminsiteirng the anti-ICAM-1 antisense compound of US Patent 5,591,623, with a reasonable expectation of success, because antisense compounds were known to be applicable for in vivo therapeutic use at the time the invention was made and because inhibiting ICAM-1 expression /level was known to "provide a new target for the control of inflammatory bowel disease" including pouchitis. See the last sentence on page 1040 of Patel et al. Accordingly, the instantly claimed invention would have been prima facie obvious over claimed reference methods in view of the teachings of Patel et al.